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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,122	07/31/2003	Roland F. Hebert		3947
29133	7590	06/14/2005	EXAMINER	
ROLLAND HEBERT 427 BELLEVUE AVE E. SUITE 301 SEATTLE, WA 98102			HENRY, MICHAEL C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/631,122	HEBERT, ROLLAND F.
	Examiner Michael C. Henry	Art Unit 1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 27 December 2004.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 15-19 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 15-19 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. \_\_\_\_\_.  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

The following office action is a responsive to the Amendment filed, 12/27/04.

The amendment filed 12/27/04 affects the application, 10/631,122 as follows:

1. Claims 1-14 have been canceled. New claims 15-19 have been amended. This leaves claims 15-19. Applicant's amendment has overcome the 112 rejections of claims 10-13.

The responsive to applicants' arguments is contained herein below.

Claims 15-19 are pending in application

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pappolla (WO 99/42102) in view of Shapiro (WO 92/14456).

In claim 15, applicant claims "A composition useful for the treatment of diseases or other conditions where free radicals or oxidative stress contribute to the pathogenesis comprising an effective amount of indole-3-propionic acid and chitosan whereby an effective amount of indole-3-propionic acid is added to water and then an effective amount of chitosan is added to the water to form a solution and the water is stirred and the resulting solution is filtered and dried.

Pappolla discloses that the compound, indole-3-propionic acid can be used to treat diseases or other conditions where free radicals and/or oxidative stress play a role, by administering an effective amount of an indole-3-propionic acid or a salt or ester thereof (see abstract). Papolla also discloses that the said diseases or condition include Parkinson's Disease, Lewy body dementia, amyotrophic lateral sclerosis, progressive supranuclear palsy, stroke, atherosclerosis, emphysema and cancer (see claims 17-19, pages 21 and 22). Furthermore, Papolla discloses that indole-3-propionic acid can be used to treat diseases or conditions that also include fibrillogenic disease such as Alzheimer's and prion-related encephalopathy (see claims 9-12, page 21).

Shapiro discloses that non-absorbable polyamine agents and amine-related agents such as chitosan can be used to treat symptoms of disorders relating to neurological disease including Alzheimer's and Parkinson's diseases (see abstract).

The difference between applicant's claimed composition and the composition disclosed by Pappolla is that the applicant ~~also~~ uses chitosan in his composition in addition to the same compound (indole-3-propionic acid) used by Pappolla.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Pappolla and Shapiro, to prepare a composition comprising a combination of indole-3-propionic acid and chitosan to treat diseases or other conditions where free radicals and/or oxidative stress play a role such as the neurological diseases, Alzheimer's and Parkinson's diseases, since the combination of compounds that are used to treat the same diseases or condition is well known in the art. More specifically, it is obvious to combine

individual compositions taught to have the same utility to form a new composition for the very same purpose. *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated in view of Pappolla and Shapiro, to prepare a composition comprising a combination of indole-3-propionic acid and chitosan, to treat diseases or other conditions where free radicals and/or oxidative stress play a role such as the neurological diseases, Alzheimer's and Parkinson's diseases, because a skilled artisan would reasonably be expected to prepare a composition comprising a combination of the compounds taught by Pappolla and Shiparo, to treat said diseases or conditions based on type and/or severity of the disease or condition.

In claim 16, applicant claims "A method for treating disease or other conditions where free radicals or oxidative stress contribute to the pathogenesis comprising administering to a mammal in need of such treatment an amount of the composition of claim 15 effective for the treatment of said disease or condition." Claims 17 and 18 are drawn to a method of claim 16 wherein the administration includes systemic, oral, topical and inhalation and the diseases includes Parkinson's disease and Alzheimer's. Claim 19 is drawn to a method of claim 16, wherein the disease or condition is selected from fibrillogenic disease and prion-related encephalopathy.

Pappolla discloses a method of treating diseases or other conditions where free radicals and/or oxidative stress play a role, by administering an effective amount of an indole-3-propionic acid or a salt or ester thereof to a human subject (see abstract). Papolla's method of treatment include the diseases or condition include Parkinson's Disease, Lewy body dementia, amyotrophic lateral sclerosis, progressive supranuclear palsy, stroke, atherosclerosis, emphysema and cancer (see

claims 17-19, pages 21 and 22). Furthermore, Papolla discloses that indole-3-propionic acid can be used to treat diseases or conditions that also include fibrillogenic disease such as Alzheimer's and prion-related encephalopathy (see claims 9-12, page 21).

Shapiro discloses that non-absorbable polyamine agents and amine-related agents such as chitosan can be used to treat symptoms of disorders relating to neurological disease including Alzheimer's (a fibrillogenic disease) and Parkinson's diseases (see abstract).

The difference between applicant's claimed method and the method disclosed by Papolla is that the applicant also uses chitosan in his composition in addition to the same compound (indole-3-propionic acid) used by Papolla.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Papolla and Shapiro, to use the method of Papolla to treat diseases or other conditions where free radicals and/or oxidative stress play a role such as the neurological diseases, Alzheimer's and Parkinson's diseases with a composition comprising a combination of indole-3-propionic acid and chitosan, since the combination of compounds that are used to treat the same diseases or condition is well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated in view of Papolla and Shapiro, to use the method of Papolla to treat diseases or other conditions where free radicals and/or oxidative stress play a role such as the neurological diseases, Alzheimer's and Parkinson's diseases with a composition comprising a combination of indole-3-propionic acid and chitosan,

because a skilled artisan would reasonably be expected to prepare a composition comprising a combination of the compounds taught by Pappolla and Shiparo, to treat said diseases or conditions based on type and/or severity of the disease or condition . It should be noted that skin aging which include wrinkles of the skin; dry skin and discolorations, with loss of elasticity and flexibility is also be associated with diseases such as atherosclerosis, cancer, diabetes, stroke and asthma, and consequently such a treatment of these diseases as claimed by applicant also encompasses a treatment of aging skin.

***Response to Arguments***

Applicant's arguments with respect to claim 15-19 have been considered but are not found convincing.

The applicant argues that there is no justification in Pappolla and Shapiro or in any other prior art separate from the applicant's disclosure that suggests these references be combined much less be combined in the manner proposed. However, Pappolla and Shapiro disclose different compounds (i.e. indole-3-propionic acid and chitosan, respectively) to treat the same diseases (for example alzheimer's and parkinson's'). Consequently one would be motivated to prepare a composition comprising a combination these compounds to treat the same said disease. The applicant argues that Pappolla discusses the important anti-oxidant effects of indole-3-propionic acid without considering any relation to carbonyl compounds in the diet as having a basis in the pathogenesis of, for example, fibrillogenic diseases. Shapiro does not discuss antioxidant effect of indole-3-propionic acid. However, Pappolla and Shapiro disclose different compounds (i.e. indole-3-propionic acid and chitosan, respectively) to treat the same diseases

(for example alzheimer's and parkinson's'). Consequently one would be motivated to prepare a composition comprising a combination these compounds to treat the same said disease.

The applicant argues that even if Pappolla and Shapiro were to be combined in the manner proposed, the proposed combination would not show any or all of the novel physical features of claim 15 (new). The novel physical features of claim 15 (new) produce new and unexpected results and hence are unobvious and patentable over these references. However, applicant's claim 15 is a composition claim comprising indole-3-propionic acid and chitosan and the intended use or manner in which the composition is produced is does not further limit the claimed composition nor present an novel features. Furthermore, has not demonstrated that the combination of indole-3-propionic acid and chitosan shows an unexpected synergistic effect over the single substance indole-3-propionic acid and the single substance chitosan, which is the combination used in the examiner's rejection. Applicant is invited to demonstrate that the combination of indole-3-propionic acid and chitosan shows an unexpected synergistic effect over the single substance indole-3-propionic acid and the single substance chitosan. Applicant argues that the patent application teaches the use of a new chemical entity that results from adding poorly water-soluble indole-3-propionic acid to water, stirring, then adding water-insoluble chitosan. The chemical reaction resulting from this produces a new compound never before seen. The compound is a conjugate chitosan-indole-3-propionic acid that has properties distinctively different from each of its constituent components. However, applicant has not claimed a compound that is a conjugate chitosan-indole-3-propionic acid.

The applicant argues that Pappolla does not disclose the use of chitosan to make a conjugate with indole-3-propionic acid to make it water-soluble. However, applicant has not

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claimed a compound that is a conjugate chitosan-indole-3-propionic acid or a method of producing the same.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.



**ELVIS Q. PRICE, PH.D.  
PRIMARY EXAMINER**

MCH

June 10, 2005.